Message Text

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PAGE 01 STATE 170497
ORIGIN HEW-06

INFO OCT-01 EUR-12 EA-09 ISO-00 OES-07 /035 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:PFF
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH: RBUHRICH, M.D.
EUR/NE:JPSHUMATE(INFO)
EA/ANP:BGALLAGHER(INFO)
----------022530 212003Z /63
P 211819Z JUL 77
FM SECSTATE WASHDC
TO AMEMBASSY LONDON PRIORITY
AMEMBASSY CANBERRA

UNCLAS STATE 170497

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, AS, UK

SUBJECT: FDA ADVISORY - POSSIBLE DEFECTIVE CARDIAC PACEMAKERS (RECALL T-121-7)

1. FDA ADVISES OF THE FOLLOWING "RECALL":

PRODUCT INVOLVED: MODELS 3821T, 3821HT, 3821ET, 3821TRC, 3821HTRC, AND 382IETRC R WAVE DEMAND MERCURY POWERED IMPLANTABLE CARDIAC PULSE GENERATORS MANUFACTURED FROM JULY 1974 TO NOVEMBER 1975.

PRODUCT INDENTIFICATION: ALL SUBJECT PACERS BEAR A LABEL ON THE IMMEDIATE DEVICE STATING "DEMAND 3821 LICENSED BY DEVICES IMPLANTS ----- STIMTECH USA." THE BLANK IS COMPLETED BY A SIX CHARACTER SERIAL NUMBER. THE FIRST CHARACTER IS AN ALPHA CHARACTER INDICATING MONTH MANUFACTURED (I.E. A JAN., B FEB., C MARCH, D APRIL, E MAY, F JUNE, G JULY,
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H AUGUST, J SEPT., K OCTOBER, L NOVEMBER, M DECEMBER. THE SECOND CHARACTER INDICATES THE YEAR MANUFACTURED (I.E. 4 1974, 5 1975). THE THIRD CHARACTER IS AN ALPHA CHARACTER INDICATING MODEL (G MODEL 3821HT OR 3821 HTRC, E MODEL 3821T OR 3821TRC, AND F ET OR ETRC). THE LAST THREE CHARACTERS OF THE S/N IS A SEQUENTIAL MANUFACTURING NUMBER.

PACERS SUBJECT TO THIS ADVISORY INCLUDE ALL 3821 MODELS MANUFACTURED FROM JULY 1974 TO NOVEMBER 1975. THIS INCLUDES ALL SERIAL NUMBERS WITH A SECOND CHARACTER OF 4. IT ALSO INCLUDES ALL SERIAL NUMBERS WITH A SERIAL NUMBER CHARACTER 5 AND WHOSE FIRST CHARACTER OF S/N IS A, B, C, D, E, F, G, H, J, K. NOTE: NO I CHARACTER WAS PRODUCED.

MANUFACTURER/RECALLING FIRM: STIMULATION TECHNOLOGY, INCORPORATED, 9440 SCIENCE CENTER DRIVE, MINNEAPOLIS, MINNESOTA, 55428.

2. REASON FOR ADVISORY (RECALL RECOMMENDATION): PENETRATION OF WATER VAPOR AND/OR BODY FLUID ALONG THE OUTPUT WIRE OF A PATIENT IMPLANTED PACEMAKER CAN AND HAS RESULTED IN INCIDENCE OF IMMEDIATE CESSATION OF PULSE GENERATION BY THE PACEMAKER. THIS IS BROUGHT ABOUT BY AN ELECTRO-CHEMICAL PROCESS AT THE TERMINAL WHICH EVENTUALLY FORMS A SHUNT CAUSING A SHORT CIRCUIT. THIS PHENOMENON HAS BEEN TERMED "METAL PLATING" (METALIC SHUNT ACROSS AN ELECTRICAL TERMINAL.)" AS PREVIOUSLY NOTED, THIS MAY RESULT IN SUDDEN CESSATION OF PACER OUTPUT WITHOUT WARNING. THE FAILURE MECHANISM WAS FOUND TO BE TIME DEPENDENT WITH THE HIGHEST FAILURE RATE OCCURRING AFTER APPROXIMATELY 15 MONTHS OF IMPLANT. THE FIRM REPORTS NO KNOWN PATIENT INJURIES OR DEATHS AS A RESULT OF THE UNCLASSIFIED

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FAILURE MECHANISM. THE FIRM'S ANALYSIS INDICATED THE FAILURE PHENOMENON IS OCCURRING IN PACERS MANUFACTURED FROM JULY 1974 TO NOVEMBER 1975. BASED UPON THE AVAILABLE DATA, AN INCIDENCE RATE OF THIS PHENOMENON FOR THESE UNITS IS LESS THAN 0.1 PER MONTH FOR THE FIRST YEAR FOLLOWING IMPLANT. IT INCREASES TO A PEAK OF APPROXIMATELY 0.6 PER MONTH FOR INTERVAL 15-21 MONTHS FOLLOWING IMPLANT. DURING 1975, SEVERAL CHANGES WERE MADE IN THE FIRM'S MANUFACTURING PROCEDURES FOR THE PACERS. THREE OF THESE CHANGES ARE BELIEVED TO HAVE ELIMINATED THE OCCURRENCE OF THE FAILURE PHENOMENON. THE FIRM STATES THAT THERE HAVE BEEN NO FAILURE OF POST NOVEMBER 1975 PACERS.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED THE MAY 1977 PHYSICIAN'S ADVISORY WHICH INDICATES THE ACTION TO BE TAKEN. IN ESSENCE, THIS ADVISORY STATES THAT IF THE PHYSICIAN'S MEDICAL JUDGMENT IS THAT A PARTICULAR PATIENT IS TOTALLY DEPENDENT ON HIS/HER PULSE GENERATOR AND WILL NOT RETURN TO SPONTANEOUS RHYTHM IN THE EVENT OF A SUDDEN PACEMAKER FAILURE, THE PHYSICIAN SHOULD EVALUATE EACH SUCH PATIENT AND REPLACE THE PULSE GENERATOR IF THE PHYSICIAN CON-

SIDERS REPLACEMENT APPROPRIATE. IN PATIENTS WHO ARE NOT PACER DEPENDENT, THE PHYSICIAN SHOULD CONSIDER

EITHER INCREASED MONITORING, WHICH COULD DETECT A PULSE GENERATOR WHICH HAS ALREADY FAILED, OR ELECTIVE REPLACEMENTS. IF REPLACEMENT IS ELECTED, STIMULATION TECHNOLOGY INCORPORATED WILL PROVIDE A NEW PACEMAKER AT NO CHARGE.

4. FOREIGN CONSIGNEES AS FOLLOWS:

DEVICES LIMITED
26-28 HYDE WAY
WELWYN GARDEN CITY
HERTFORDSHIRE AL7 3AP
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ENGLAND

NEO-MEDIX (FORMALLY DEVICES PTY. LTD.)
A.E. WYNTER
21 MOORAMBA ROAD
DEE WHY
SYDNEY, N.W., AUSTRALIA 2099

VANCE

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
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Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 21-Jul-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
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To: LONDON CANBERRA
Type: TE
vdkvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/43d3ea65-c288-dd11-92da-001cc4696bcc
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